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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,067	06/28/2002	Mats Paulsson	HLZ-001US	7795

			EXAMINER
959	7590	08/25/2006	COUNTS, GARY W

LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
10/019,067	06/28/02	Paulsson, Mats	HLZ-001US

EXAMINER
Counts

ART UNIT	PAPER
1641	08/18/06

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents

The communication filed on **08/07/06** is not fully responsive to the Office communication mailed **02/06/06** for the reason(s) set forth on the attached Notice to Comply With the Sequence Rules or CRF Diskette Problem Report.

Since the above mentioned reply appears to be *bona fide*, applicant is given a TIME PERIOD of ONE (1) MONTH or THIRTY DAYS from the mailing date of this notice, which ever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER C.F.R. 1.136(a).

The addresses below are effective 5 June 2004. Please direct all replies to the United States Patent and Trademark Office via one (1) of the following:
1. Electronically submitted through EFS-Bio (<http://www.uspto.gov/ebc/efs/downloads/documents.htm>, EFS Submission User Manual - ePAVE)
2. Mailed to:
   Mail Stop Sequence
   Commissioner for Patents
   P.O. Box 22313-1450
   Alexandria, VA 22313-1450
3. Hand Carry, Federal Express, United Parcel Service or other delivery service to:
   U.S. Patent and Trademark Office
   Mail Stop Sequence
   Customer Window
   Randolph Building

PTO-90C (Rev.3-98)

	Application No.	Applicant(s)
Notice to Comply	10/019,067	Paulsson et al.
	Examiner	Art Unit	
	Counts	1641	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: *See Sequence Listing error Report.*

Applicant Must Provide:
☐ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application.**

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216 or (703) 308-2923
For CRF Submission Help, call (703) 308-4212 or 308-2923
PatentIn Software Program Support
    Technical Assistance.......................................703-287-0200
    To Purchase PatentIn Software.......................703-306-2600

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY

401 Dulaney Street

Alexandria, VA 22314

Any inquiry concerning this communication should be directed to Examiner **Gary Counts,** Art Unit **1641,** whose telephone number is (571) 272-0817.

LONG V. LE   03/13/06
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Sequence Count Sheet	Application/Control No.	Applicant(s)	
	10/019,067	Paulsson et al.	
	Examiner	Art Unit	
	Counts	1641	

DATE OF COUNT

Mark only one space below

☐   **(CRFN)** (CRF is unreadable; use CRF Diskette Problem Report)

☒   **(CRFD)** (CRF does not comply; use Notice to Comply)

☐   **(CRFR)** (CRF required but none submitted; use Notice to Comply)

☐   **(bona fide)** (second or subsequent letter to applicant reporting bona fide attempt to comply; use Notice to Comply and send copy of RSL)

☐   **(non bona fide)** (second or subsequent letter to applicant reporting non-bona fide attempt to comply; use Notice to Comply and send copy of RSL)

STIC Biotechnology Systems Branch

RAW SEQUENCE LISTING
ERROR REPORT

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number: _10/019,067_

Source: _TFW16_

Date Processed by STIC: _08/10/2006_

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.
PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:
1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,
2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY
FOR CRF SUBMISSION AND PATENTIN SOFTWARE QUESTIONS, PLEASE CONTACT MARK SPENCER, TELEPHONE: 571-272-2510; FAX: 571-273-0221

TO **REDUCE** ERRORED SEQUENCE LISTINGS, **PLEASE** USE THE **CHECKER VERSION 4.4.0 PROGRAM**, ACCESSIBLE THROUGH THE U.S. PATENT AND TRADEMARK OFFICE WEBSITE. SEE BELOW FOR ADDRESS:
     http://www.uspto.gov/web/offices/pac/checker/chkrnote.htm

Applicants submitting genetic sequence information electronically on diskette or CD-Rom should be aware that there is a possibility that the disk/CD-Rom may have been affected by treatment given to all incoming mail.
Please consider using alternate methods of submission for the disk/CD-Rom or replacement disk/CD-Rom.
Any reply including a sequence listing in electronic form should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office, and instead should be sent via the following to the indicated addresses:

1. EFS-Bio (<http://www.uspto.gov/ebc/efs/downloads/documents.htm> , **EFS Submission User Manual** - ePAVE)
2. **U.S. Postal Service:** Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450
3. **Hand Carry, Federal Express, United Parcel Service, or other delivery service (EFFECTIVE 01/14/05):**
     U.S. Patent and Trademark Office, Mail Stop Sequence, Customer Window, Randolph Building, 401 Dulany Street, Alexandria, VA 22314

Revised 01/10/06

IFW16

RAW SEQUENCE LISTING   DATE: 08/10/2006
PATENT APPLICATION: US/10/019,067   TIME: 08:57:49

Input Set : **A:\Sequence Listing.txt**
Output Set: **N:\CRF4\08102006\J019067.raw**

```
   5 <110> APPLICANT: Immundiagnostik AG
   7         Wieslab AB
   9         PAULSSON, Mats
  11         SMYTH, Neil
  13         AESCHLIMANN, Daniel
  15         KARPATI, Sarolta
  17         ODENTHAL, Uwe
  19         SARDY, Miklos
  23 <120> TITLE OF INVENTION: DIAGNOSIS OF GLUTEN SENSITIVE ENTEROPATHY AND OTHER
AUTOIMMUNOPATHIES
  27 <130> FILE REFERENCE: HLZ-001 US (GP968US00)
C--> 31 <140> CURRENT APPLICATION NUMBER: US/10/019,067
C--> 33 <141> CURRENT FILING DATE: 2002-06-28
  37 <150> PRIOR APPLICATION NUMBER: EP 99111075.1
  39 <151> PRIOR FILING DATE: 1999-06-28
  43 <160> NUMBER OF SEQ ID NOS: 16
  47 <170> SOFTWARE: PatentIn version 3.1
  51 <210> SEQ ID NO: 1
  53 <211> LENGTH: 33
  55 <212> TYPE: DNA
  57 <213> ORGANISM: Artificial
W--> 61 <220> FEATURE:
W--> 61 <223> OTHER INFORMATION:
W--> 61 <400> 1
  62 ggccgcatgg agccatccac aattcgaaaa gta
  65 <210> SEQ ID NO: 2
  67 <211> LENGTH: 33
  69 <212> TYPE: DNA
  71 <213> ORGANISM: Artificial
W--> 75 <220> FEATURE:
W--> 75 <223> OTHER INFORMATION:
W--> 75 <400> 2
  76 ggcctacttt tcgaattgtg gatggctcca tgc
  79 <210> SEQ ID NO: 3
  81 <211> LENGTH: 36
  83 <212> TYPE: DNA
  85 <213> ORGANISM: Artificial
W--> 89 <220> FEATURE:
W--> 89 <223> OTHER INFORMATION:
W--> 89 <400> 3
  90 attaagcttg ccgccaccat ggccgaggag ctggtc
  93 <210> SEQ ID NO: 4
  95 <211> LENGTH: 30
  97 <212> TYPE: DNA
```

Does Not Comply
Corrected Diskette Needed

(pg – 1, 2, 3)

If <213> Responses are Artificial, Unknown. Pls explain the source of genetic material. See pg-5 for Error Explanation.

33

33

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RAW SEQUENCE LISTING   DATE: 08/10/2006
PATENT APPLICATION: US/10/019,067   TIME: 08:57:49
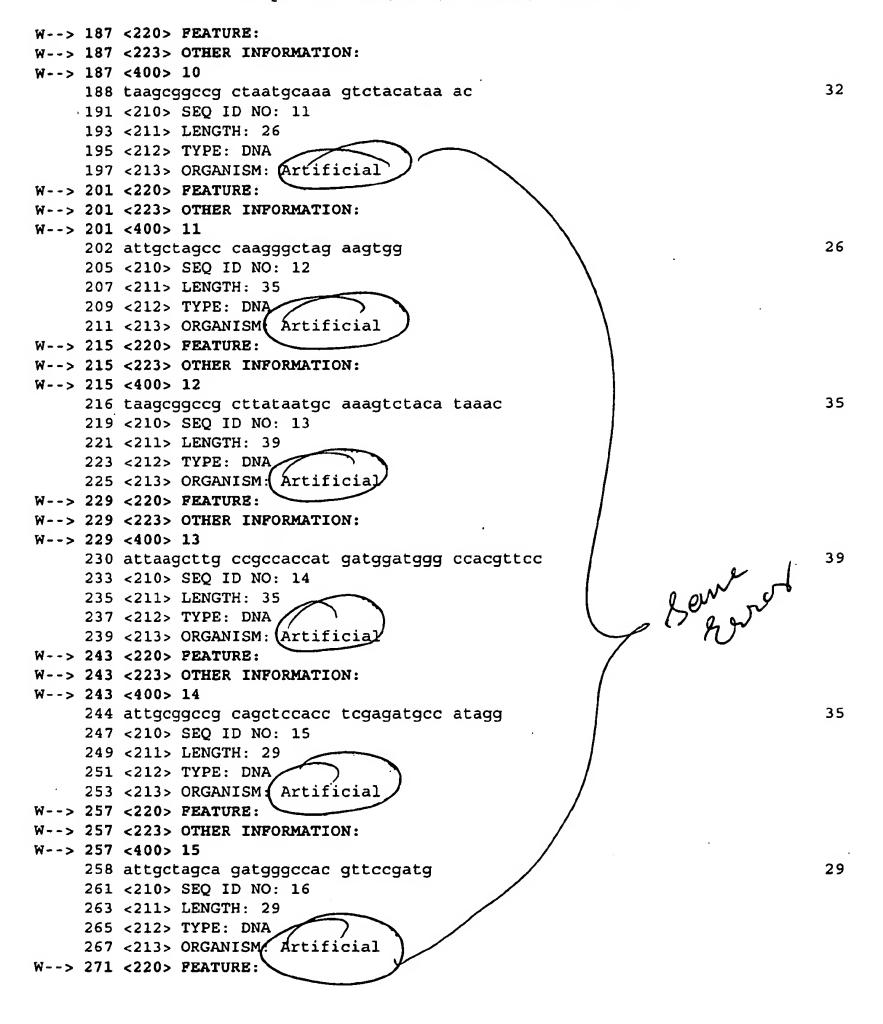
Input Set : A:\Sequence Listing.txt
Output Set: N:\CRF4\08102006\J019067.raw

```
        99 <213> ORGANISM: Artificial
W-->   103 <220> FEATURE:
W-->   103 <223> OTHER INFORMATION:
W-->   103 <400> 4
       104 taagcggccg cggggccaat gatgacattc                              30
       107 <210> SEQ ID NO: 5
       109 <211> LENGTH: 36
       111 <212> TYPE: DNA
       113 <213> ORGANISM: Artificial
W-->   117 <220> FEATURE:
W-->   117 <223> OTHER INFORMATION:
W-->   117 <400> 5
       118 attaagcttg ccgccaccat ggctgctcta ggagtc                       36
       121 <210> SEQ ID NO: 6
       123 <211> LENGTH: 33
       125 <212> TYPE: DNA
       127 <213> ORGANISM: Artificial
W-->   131 <220> FEATURE:
W-->   131 <223> OTHER INFORMATION:
W-->   131 <400> 6
       132 attgcggccg cttcggctac atcgatggac aac                          33
       135 <210> SEQ ID NO: 7
       137 <211> LENGTH: 46
       139 <212> TYPE: DNA
       141 <213> ORGANISM Artificial
W-->   145 <220> FEATURE:
W-->   145 <223> OTHER INFORMATION:
W-->   145 <400> 7
       146 ctagttgccg ccaccatggc ttggagccat ccacaattcg aaaagg            46
       149 <210> SEQ ID NO: 8
       151 <211> LENGTH: 48
       153 <212> TYPE: DNA
       155 <213> ORGANISM: Artificial
W-->   159 <220> FEATURE:
W-->   159 <223> OTHER INFORMATION:
W-->   159 <400> 8
       160 ctagcgcctt ttcgaattgt ggatggctcc aagccatggt ggcggcaa          48
       163 <210> SEQ ID NO: 9
       165 <211> LENGTH: 31
       167 <212> TYPE: DNA
       169 <213> ORGANISM Artificial
W-->   173 <220> FEATURE:
W-->   173 <223> OTHER INFORMATION:
W-->   173 <400> 9
       174 attgcggccg ccatggccca agggctagaa g                            31
       177 <210> SEQ ID NO: 10
       179 <211> LENGTH: 32
       181 <212> TYPE: DNA
       183 <213> ORGANISM: Artificial
```

7 Same Error

RAW SEQUENCE LISTING   DATE: 08/10/2006
PATENT APPLICATION: US/10/019,067   TIME: 08:57:49

Input Set : **A:\Sequence Listing.txt**
Output Set: **N:\CRF4\08102006\J019067.raw**

```
W--> 187 <220> FEATURE:
W--> 187 <223> OTHER INFORMATION:
W--> 187 <400> 10
     188 taagcggccg ctaatgcaaa gtctacataa ac                    32
    ·191 <210> SEQ ID NO: 11
     193 <211> LENGTH: 26
     195 <212> TYPE: DNA
     197 <213> ORGANISM: Artificial
W--> 201 <220> FEATURE:
W--> 201 <223> OTHER INFORMATION:
W--> 201 <400> 11
     202 attgctagcc caagggctag aagtgg                           26
     205 <210> SEQ ID NO: 12
     207 <211> LENGTH: 35
     209 <212> TYPE: DNA
     211 <213> ORGANISM: Artificial
W--> 215 <220> FEATURE:
W--> 215 <223> OTHER INFORMATION:
W--> 215 <400> 12
     216 taagcggccg cttataatgc aaagtctaca taaac                 35
     219 <210> SEQ ID NO: 13
     221 <211> LENGTH: 39
     223 <212> TYPE: DNA
     225 <213> ORGANISM: Artificial
W--> 229 <220> FEATURE:
W--> 229 <223> OTHER INFORMATION:
W--> 229 <400> 13
     230 attaagcttg ccgccaccat gatggatggg ccacgttcc            39
     233 <210> SEQ ID NO: 14
     235 <211> LENGTH: 35
     237 <212> TYPE: DNA
     239 <213> ORGANISM: Artificial
W--> 243 <220> FEATURE:
W--> 243 <223> OTHER INFORMATION:
W--> 243 <400> 14
     244 attgcggccg cagctccacc tcgagatgcc atagg                35
     247 <210> SEQ ID NO: 15
     249 <211> LENGTH: 29
     251 <212> TYPE: DNA
     253 <213> ORGANISM: Artificial
W--> 257 <220> FEATURE:
W--> 257 <223> OTHER INFORMATION:
W--> 257 <400> 15
     258 attgctagca gatgggccac gttccgatg                        29
     261 <210> SEQ ID NO: 16
     263 <211> LENGTH: 29
     265 <212> TYPE: DNA
     267 <213> ORGANISM: Artificial
W--> 271 <220> FEATURE:
```

RAW SEQUENCE LISTING   DATE: 08/10/2006
PATENT APPLICATION: US/10/019,067   TIME: 08:57:49

          Input Set : A:\Sequence Listing.txt
          Output Set: N:\CRF4\08102006\J019067.raw

W--> 271 <223> OTHER INFORMATION:
W--> 271 <400> 16
     272 attggatcct aagctccacc tcgagatgc   29

RAW SEQUENCE LISTING ERROR SUMMARY   DATE: 08/10/2006
PATENT APPLICATION: US/10/019,067   TIME: 08:57:50

Input Set : **A:\Sequence Listing.txt**
Output Set: **N:\CRF4\08102006\J019067.raw**

Invalid <213> Response:
Use of "Artificial" only as "<213> Organism" response is incomplete,
per 1.823(b) of New Sequence Rules. Valid response is Artificial Sequence.

Seq#:1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16

Error Explanation

Use of <220> Feature(NEW RULES):
Sequence(s)__are missing the <220> Feature and associated headings.
Use of <220> to <223> is **MANDATORY** if <213> ORGANISM is "Artificial Sequence"
or"Unknown". Please explain source of genetic material in <220> to <223>
section (See "Federal Register," 6/01/98, Vol. 63, No. 104,pp.29631-32)
(Sec.1.823 of new Rules)

Seq#:1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16

VERIFICATION SUMMARY   DATE: 08/10/2006
PATENT APPLICATION: US/10/019,067   TIME: 08:57:50

Input Set : **A:\Sequence Listing.txt**
Output Set: **N:\CRF4\08102006\J019067.raw**

L:31 M:270 C: Current Application Number differs, Replaced Current Application Number
L:33 M:271 C: Current Filing Date differs, Replaced Current Filing Date
L:61 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ#:1, <213>
ORGANISM:Artificial
L:61 M:258 W: Mandatory Feature missing, <223> Tag not found for SEQ#:1, <213>
ORGANISM:Artificial
L:61 M:258 W: Mandatory Feature missing, <223> Blank for SEQ#:1,Line#:61
L:75 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ#:2, <213>
ORGANISM:Artificial
L:75 M:258 W: Mandatory Feature missing, <223> Tag not found for SEQ#:2, <213>
ORGANISM:Artificial
L:75 M:258 W: Mandatory Feature missing, <223> Blank for SEQ#:2,Line#:75
L:89 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ#:3, <213>
ORGANISM:Artificial
L:89 M:258 W: Mandatory Feature missing, <223> Tag not found for SEQ#:3, <213>
ORGANISM:Artificial
L:89 M:258 W: Mandatory Feature missing, <223> Blank for SEQ#:3,Line#:89
L:103 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ#:4, <213>
ORGANISM:Artificial
L:103 M:258 W: Mandatory Feature missing, <223> Tag not found for SEQ#:4, <213>
ORGANISM:Artificial
L:103 M:258 W: Mandatory Feature missing, <223> Blank for SEQ#:4,Line#:103
L:117 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ#:5, <213>
ORGANISM:Artificial
L:117 M:258 W: Mandatory Feature missing, <223> Tag not found for SEQ#:5, <213>
ORGANISM:Artificial
L:117 M:258 W: Mandatory Feature missing, <223> Blank for SEQ#:5,Line#:117
L:131 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ#:6, <213>
ORGANISM:Artificial
L:131 M:258 W: Mandatory Feature missing, <223> Tag not found for SEQ#:6, <213>
ORGANISM:Artificial
L:131 M:258 W: Mandatory Feature missing, <223> Blank for SEQ#:6,Line#:131
L:145 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ#:7, <213>
ORGANISM:Artificial
L:145 M:258 W: Mandatory Feature missing, <223> Tag not found for SEQ#:7, <213>
ORGANISM:Artificial
L:145 M:258 W: Mandatory Feature missing, <223> Blank for SEQ#:7,Line#:145
L:159 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ#:8, <213>
ORGANISM:Artificial
L:159 M:258 W: Mandatory Feature missing, <223> Tag not found for SEQ#:8, <213>
ORGANISM:Artificial
L:159 M:258 W: Mandatory Feature missing, <223> Blank for SEQ#:8,Line#:159
L:173 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ#:9, <213>
ORGANISM:Artificial
L:173 M:258 W: Mandatory Feature missing, <223> Tag not found for SEQ#:9, <213>
ORGANISM:Artificial
L:173 M:258 W: Mandatory Feature missing, <223> Blank for SEQ#:9,Line#:173
L:187 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ#:10, <213>
ORGANISM:Artificial
L:187 M:258 W: Mandatory Feature missing, <223> Tag not found for SEQ#:10, <213>
ORGANISM:Artificial
L:187 M:258 W: Mandatory Feature missing, <223> Blank for SEQ#:10,Line#:187
L:201 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ#:11, <213>

```
ORGANISM:Artificial
L:201 M:258 W: Mandatory Feature missing, <223> Tag not found for SEQ#:11, <213>
ORGANISM:Artificial
L:201 M:258 W: Mandatory Feature missing, <223> Blank for SEQ#:11,Line#:201
L:215 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ#:12, <213>
ORGANISM:Artificial
L:215 M:258 W: Mandatory Feature missing, <223> Tag not found for SEQ#:12, <213>
ORGANISM:Artificial
L:215 M:258 W: Mandatory Feature missing, <223> Blank for SEQ#:12,Line#:215
L:229 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ#:13, <213>
ORGANISM:Artificial
L:229 M:258 W: Mandatory Feature missing, <223> Tag not found for SEQ#:13, <213>
ORGANISM:Artificial
L:229 M:258 W: Mandatory Feature missing, <223> Blank for SEQ#:13,Line#:229
L:243 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ#:14, <213>
ORGANISM:Artificial
L:243 M:258 W: Mandatory Feature missing, <223> Tag not found for SEQ#:14, <213>
ORGANISM:Artificial
L:243 M:258 W: Mandatory Feature missing, <223> Blank for SEQ#:14,Line#:243
L:257 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ#:15, <213>
ORGANISM:Artificial
L:257 M:258 W: Mandatory Feature missing, <223> Tag not found for SEQ#:15, <213>
ORGANISM:Artificial
L:257 M:258 W: Mandatory Feature missing, <223> Blank for SEQ#:15,Line#:257
L:271 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ#:16, <213>
ORGANISM:Artificial
```

VERIFICATION SUMMARY   DATE: 08/10/2006
PATENT APPLICATION: US/10/019,067   TIME: 08:57:50

Input Set : A:\Sequence Listing.txt
Output Set: N:\CRF4\08102006\J019067.raw

L:271 M:258 W: Mandatory Feature missing, <223> Tag not found for SEQ#:16, <213>
ORGANISM:Artificial
L:271 M:258 W: Mandatory Feature missing, <223> Blank for SEQ#:16,Line#:271